

**REMARKS/ARGUMENTS**

Applicants respectfully request reconsideration and continued examination of the above-identified application. Claims 1-3 and 5-23 remain pending in the application. By this Amendment, Applicants amend claims 1, 5, 6, and 23, and cancel claim 4 without prejudice or disclaimer. Claims 2, 3, and 10-22 have been withdrawn from consideration. Support for the amended claims can be found in the present application, for example, at least in paragraph [0057], and Example 1, paragraphs [0151]-[0154] of the original specification and in the original claims as filed. Accordingly, no questions of new matter should arise and Applicants respectfully request entry of this amendment.

**Rejection of claims 1, 4-9, and 23 under 35 U.S.C. §112, second paragraph**

At page 3 of the Office Action, the Examiner rejects claims 1, 4-9, and 23 under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

In claims 1 and 23, the Examiner requests clarification of the polynucleotide and complementary nucleotide sequences. Amended claims 1 and 23 each further clarifies the features of the claimed polynucleotides and nucleotide sequences complementary thereto. Amended claim 23 also further clarifies the features of the claimed reagent kit, and deletes a specific reference to withdrawn claim 10. Thus, amended claims 1 and 23 satisfy the requirements of 35 U.S.C. §112, second paragraph.

In claim 4, the Examiner requests clarification to the 70% homology criterion. Claim 4 has been canceled, thus rendering moot this rejection.

In claim 5, the Examiner requests clarification to an “induced mutation” as compared to a “mutation.” Amended claim 5 is directed to an “isolated polynucleotide with a mutation” and

deletes the feature of “an induced mutation.” Thus, amended claim 5 satisfies the requirements of 35 U.S.C. §112, second paragraph.

Thus, each of claims 1, 5-9, and 23 satisfies the requirements of 35 U.S.C. §112, second paragraph. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

**Rejection of claims 1, 4-9, and 23 under 35 U.S.C. §102(b)**

At page 4 of the Office Action, the Examiner rejects claims 1, 4-9, and 23 under 35 U.S.C. §102(b) as being anticipated by Venter et al. (WO 2002/068579 A2). Applicants respectfully traverse this rejection.

Amended claim 1 is directed to an isolated polynucleotide comprising a nucleotide sequence selected from the group consisting of: (a) the nucleotide sequence set forth in SEQ ID NO: 1, (b) a nucleotide sequence encoding a protein comprising the amino acid sequence set forth in SEQ ID NO: 2, or (c) a nucleotide sequence complementary to a polynucleotide defined in (a) or (b). Venter et al. fails to teach or suggest such polynucleotides, and furthermore, fails to serve as an enabling reference for §102(b) purposes.

Venter et al. describes primary nucleotide sequences of the coding portions of the human genome from a series of predicted gene transcript sequences generated from the assembled and annotated human genome (SEQ ID NOS: 1-39010). Venter et al. includes SEQ ID NO: 16323 which has homology to a portion of the nucleotide sequence of presently claimed SEQ ID NO: 1. Venter, however, fails to disclose an isolated polynucleotide having the nucleotide sequence of SEQ ID. NO: 1, SEQ ID NO: 2, and/or complementary nucleotide sequences. The thousands of “predicted” transcript sequences described in Venter et al. were merely the results of computer-

generated analysis of the human genome (*see*, Venter et al., page 11). Venter et al. never isolated any polynucleotides, and more importantly, never isolated the polynucleotides of SEQ ID NO: 1, SEQ ID NO: 2, or polynucleotides complementary thereto as presently featured in claim 1. Thus, for this reason alone, Venter et al. fails to teach the polynucleotides having all of the features recited in claim 1.

Venter et al. also fails to sufficiently enable a person of ordinary skill in the art to make the claimed invention, and therefore, Venter et al. cannot even be considered as a prior art reference for purposes of a §102(b) rejection. A prior art reference must be as enabling as that required for U.S. patents under 35 U.S.C. §112, first paragraph. The description must enable a person with ordinary skill in the art to not only comprehend the invention, but also to make it. As stated in the MPEP, “the disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation.” *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003) (*see*, MPEP 2121.01). Venter et al. utilized the annotated human genome sequence database and computer software that predicted intron and exon gene sequences and putative splice sites, and generated potential or presumed gene transcripts. Venter et al., however, fails to provide any guidance as to how to produce the isolated polynucleotides as claimed, and fails to provide any actual examples of experimental procedures to enable a person of ordinary skill in the art to make the claimed invention without undue experimentation.

As further evidence of the failure of Venter et al. to enable the claimed invention, Venter et al. and its computer system fail to even predict the complete sequence of a gene isolated by Applicants in this invention, i.e., a gene coding for a protein that accelerates the activation of

Cdc42. Applicants describe in the present specification, and feature in part in claim 1, a nucleotide sequence set forth in SEQ ID NO: 1, or a nucleotide sequence encoding a protein comprising the amino acid sequence set forth in SEQ ID NO: 2. Utilizing the full human genome sequence data and its computer system, Venter et al. proposes SEQ ID NO: 16323, a nucleotide sequence that encodes only a portion (nucleotide 880 to 1658) of SEQ ID NO: 1, and thus, fails to teach or suggest or predict the polynucleotides invented by Applicants. The predictions made by Venter et al. falls short of the presently claimed isolated polynucleotides, and do not enable the isolation of the polynucleotides as claimed.

In view of the above comments, Venter et al. cannot serve as a reference for a §102(b) rejection, and furthermore, fails to teach or suggest or anticipate isolated polynucleotides comprising a nucleotide sequence selected from the group consisting of: (a) the nucleotide sequence set forth in SEQ ID NO: 1, (b) a nucleotide sequence encoding a protein comprising the amino acid sequence set forth in SEQ ID NO: 2, or (c) a nucleotide sequence complementary to a polynucleotide defined in (a) or (b), as featured in present claim 1.

Claims 5-9 depend from claim 1, and the above comments regarding claim 1 apply as well to these claims. Furthermore, claims 5 and 6 each additionally feature that the polynucleotide “encodes a protein that accelerates the activation of Cdc42.” Venter et al. fails to teach or suggest any polynucleotides having this feature. As stated above, Venter et al. proposes SEQ ID NO: 16323, a nucleotide sequence encoding only a portion (nucleotide 880 to 1658) of SEQ ID NO: 1. This partial gene fragment does not encode a protein having such Cdc42 activation property as required in claims 5 and 6. For this additional reason, Venter et al. fails to teach or suggest, and fails to anticipate claims 5 and/or 6.

Claim 23 is directed to a reagent kit comprising at least one selected from the group

consisting of: (a) a polynucleotide encoding a protein comprising the amino acid sequence set forth in SEQ ID NO: 2; (b) a polynucleotide comprising a nucleotide sequence complementary to the polynucleotide defined in (a); (c) a recombinant vector comprising said polynucleotide defined in (a) or (b); and (d) a transformant that has been transfected with the recombinant vector defined in (c). For at least the same reasons as stated in the above comments regarding claim 1, Venter et al. fails to teach or suggest the claimed reagent kit, and Venter et al. cannot serve as an enabled reference for a §102(b) rejection.

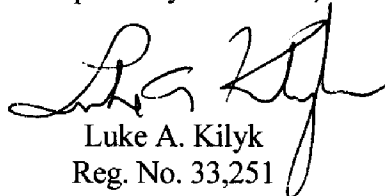
For at least these reasons, Venter et al. fails to anticipate claims 1, 5-9, and 23. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

### **CONCLUSION**

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



Luke A. Kilyk  
Reg. No. 33,251

Atty. Docket No. 3190-100  
KILYK & BOWERSOX, P.L.L.C.  
400 Holiday Court, Suite 102  
Warrenton, VA 20186  
Tel.: (540) 428-1701  
Fax: (540) 428-1720